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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,669	04/09/2004	M. Zouhair Atassi	17525 (AP)	9880

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,669	ATASSI, M. ZOUHAIR	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,31-43,48-61,63,67-73,93,94,99-101,114-121 and 123-135* is/are pending in the application.

4a) Of the above claim(s) *48-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,31-43,54-61,63,67-73,93,94,99-101,114-121 and 123-135* is/are rejected.

7)☒ Claim(s) *1-17,33-35,124,127,131,134-135* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-17, 31-43,48-61,63,67-73,93-94,96-97,99-101,114-121,123-135 are pending.
Claims 48-53 stand withdrawn from consideration
1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 9, 2006 has been entered.

Objections/Rejections Withdrawn

All prior objections and rejections are herein withdrawn in light of the newly submitted combination of claim amendments/claim limitations

3. ***Rejection Withdrawn Claim Rejections - 35 USC § 102*** Amended claims 1-13, 15,17,31-43, 54-61, 114-121,123-132 rejected under 35 U.S.C. 102(b) as being anticipated by Dertzbaugh et al (1996), in light of the amendment of the claims to recite a combination of claim limitations not disclosed by Dertzbaugh.
4. Claims 1-16, 55-61,63, 67-73, 93-94,96-101, 114-112, 123-133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dertzbaugh et al (1996) in view of Bavari et al (effective filing date 1998), in light of the amendment of the claims to recite a combination of claim limitations not disclosed by Dertzbaugh.
1. ***Rejection Withdrawn Claim Rejections - 35 USC § 102*** Claims 93 and 96 rejected under 35 U.S.C. 102(b) as being anticipated by Sesardic et al (WO94/21684) in light of the claims having been amended to no longer recite an amino acid sequence of SEQ ID NO 1, range 827-845.

New Claim Limitations/New Grounds of Rejection

Claim Objections

2. Claims 1-17 and 33-35, 124, 127,131, 134-135 are objected to because of the following informalities:

a. Claims 1-11, 14-17, 33-35, 124, 131, 134 recite at the end of paragraph 1 (claim 1 and claim dependent therefrom) the term "thereof"; a comma "," is missing before the recitation of the "wherein" clauses. All dependent claims which end a paragraph in the term "thereof" which does not show a "," comma before the recitation of a "wherein" clause should have a comma-----,------ inserted.

b. Claims 1-11,14-17 recite an improper Markush group format defined by the recitation of species "selected from the group consisting of" A, B, or C and D, species D selected from the group consisting of A, B, C. D, E and F. Proper Markush format is A, B, C and D. Each species separated by commas.

c. Claims 12-13, 15-17 are objected to for reciting a combination of claim limitations twice. The claim limitations set forth in paragraph 2 are the same limitations recited in paragraph 1 and are therefore duplicative.

d. Claims 127 and 135 are objected to for having a period at the end of paragraph 1 and before the "wherein" clause. This appears to be a typographical error. Additionally the term "1comprises" is recited in claim 135, which is a typographical error.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

. The peptides of claims 134 and 135 do not show the hand of man by being isolated and purified and therefore read on a product of nature; the claimed invention is directed to non-statutory subject matter

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-17, 31-43, 54-61,63,67-73,114-121, 123-133 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-17 recite both open and closed language which is confusing. In paragraph 1 of claim 1, the claims recite " said BoNT/A peptide consisting of an amino acid sequence selected from the group consisting of" and "an amino acid sequence selected from the group consisting of"; thus paragraph 1 defines the antibodies to be immunoreactive **two peptides** but

in paragraph 2 of claim 1, the "antibodies immunoreact with amino acids" 785-803, 981-999, 1051-1069, 1121-1139, 1275-1296, a conservative amino acid sequence variant thereof **and** an immunoreactive BoNT/A amino acid sequence fragment thereof", which defines the antibodies to be immunoreactive with **9 peptides instead** of the two peptides set forth in paragraph 1 of the claim;

in paragraph 5, the invention is redefined once again by a wherein phrase that is contradictory to the prior defined compositions of paragraphs 1 and 2 by the phrase "wherein the presence of antibodies immunoreactive with **at least one** of said BoNT/A peptides indicates

immunoresistence to a botulinum toxin therapy. The claim limitations are confusing as now claimed.

Claims 31-43 are unclear because in paragraph b) of the claims the sequence fragment is first defined by the first "wherein" clause to "stimulate an immune response" but in the second "wherein" clause the sequence fragment is redefined to be what produces the immune response by the recitation of the phrase "said immunoreactive BoNT/A amino acid sequence fragment producing an immune response" . The fragment can simulate but not produce an immune response, as T and B cell produce immune responses and not peptides. The invention is not clearly nor distinctly claimed.

6. Claims 36-43 recites the limitation "two" or "three" or "four" in reference to claim 31 which recites the term "one". There is insufficient antecedent basis for this limitation in the claim. The rejection could be obviated by amending the claims to recite: ---- wherein said additional peptides comprise peptides ----------.

7. Claims 1-17, 54-61,63,67-73 set forth the mental step of "determining" which is not positive methods step that utilizes reagents and positive methods steps. It is unclear what method/process applicant is intending to encompass by claiming a mental step of "determining". A claim is indefinite where it merely recites a nonspecific step without any active, positive steps delimiting how the method is actually practiced.

8. Claims 31-42, 123-133 and claims 114-121 recite the phrase " an immunoreactive BoNT/A amino acid sequence fragment thereof" , the method (claims 31-42) and composition (claims 114-121) being directed "producing antibodies that neutralize BoNT/A" and "An immune response inducing composition", respectively. An immunoreactive BoNT/A amino acid

sequence fragment could be as small as two amino acids (definition at [062] page 18, lines 1-2 of the instant Specification), but would not induce/produce any antibodies as the relative molecular weight of the fragment would be too small to be recognized by the host animal's immune system (needs to be at least 1000 daltons in size). The claims do not clearly set forth Applicant's invention by administering an immunoreactive fragment in order to produce or induce an immune response. All immunogenic fragments are not immunogenic and would not produce or induce an immune response. See In re Meyhew.

Claim Rejections - 35 USC § 102

Please Note: The following prior art rejections over claims 1-17 are being made of record in light of the claims reciting the methods step of "determining the presence or absence in said individual of antibodies"; the methods step reading on in vivo and in vitro methods that have one methods step of determining the presence or absence of antibodies by any means.

9. Claims 1-15,17 are rejected under 35 U.S.C. 102(b) as being anticipated by Tugnoli et al (1997) in light of evidence provided by Dolimbek et al(2007).

10. Tugnoli et al disclose the instantly claimed method, the method comprising the step of:

determining the presence or absence of antibodies in an individual (see page Tugnoli et al, section 5.5) that neutralize botulinum toxin, wherein the antibodies in the individual are determined by ELISA or mouse bioassay. While Tugnoli et al do not disclose the specific peptides the antibodies in the individual immunoreact, Dolimbek et al(2007)provides evidence of neutralizing antibodies in humans to immunoreact with the recited peptides. Tugnoli et al anticipates the instantly claimed invention as now claimed.

11. Claims 1-13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Jankovic et al (1995) in light of evidence provided by Dolimbek et al(2007).

12. Jankovic et al disclose the instantly claimed method, the method comprising the step of:

determining the presence or absence of antibodies in an individual (see page Jankovic et al, abstract and title) that neutralize botulinum toxin, wherein the antibodies in the individual are determined by no response to botulinum toxin type A injections on at least two consecutive treatment sessions (see abstract, top half). While Jankovic et al do not disclose the specific peptides the antibodies in the individual immunoreact, Dolimbek et al(2007)provides evidence of neutralizing antibodies in humans to immunoreact with the recited peptides. Jankovic et al anticipates the instantly claimed invention as now claimed.

13. Claims 1-13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanna et al (1998) in light of evidence provided by Dolimbek et al(2007).

14. Hanna et al disclose the instantly claimed method, the method comprising the step of:

determining the presence or absence of antibodies in an individual (see page Hanna et al, al, objective, conclusions (first page) and title) that neutralize botulinum toxin. While Hanna et al do not disclose the specific peptides the antibodies in the individual immunoreact, Dolimbek et al(2007) provides evidence of neutralizing antibodies in humans to immunoreact with the recited peptides. Hanna et al anticipates the instantly claimed invention as now claimed.

15. Claims 1-11, 14, and 16-17 rejected under 35 U.S.C. 102(b) as being anticipated by Oshima et al (1997).

Please Note: In light of claim 1 requiring the method to determine the "presence of antibodies immunoreactive with at least one of said BoNT/A peptides (last paragraph)" the peptides including amino acids 1275-1296, 1051-1069 and 981-999 the following prior art rejection is being applied against the claims.

Oshima et al disclose the instantly claimed method directed determining the presence of antibodies produced by an individual by radioimmunoassay (see page 1033, "RIA"), wherein the antibodies were either IgG or IgM antibodies and immunoreactive with peptides including amino acids **1275-1296, 1051-1069, 1121-1139, and 981-999** (see Table 1).

Oshima et al anticipates the instantly claimed invention which determines the presence of antibodies that are immunoreactive with at least one peptide.

16. Claims 93-94, 96-97 and 134 are rejected under 35 U.S.C. 102(b) as being anticipated by Krieglstein et al (1994).

Krieglstein et al disclose compositions of peptides obtained from botulinum neurotoxin type A:

Instant claim 93: Peptide fragment amino acids 531-539 anticipates claimed peptides 519-537 and 533-551 as the disclosed peptide comprises an amino acids sequence of the claimed range (see Figure 1, page 52).

Instant claim 93: Peptide fragment amino acids 602-608 anticipates claimed peptide 589-607 as the disclosed peptide comprises an amino acids sequence of the claimed range. (see Figure 1, page 52).

Instant claim 93: Peptide fragment amino acids 731-741 anticipates claimed peptide 715-733 as the disclosed peptide comprises an amino acids sequence of the claimed range. (see Figure 1, page 52).

Instant claim 93: Peptide fragment from amino acid 781-796 anticipates claimed peptide 771-789 and 785-803 as this peptide comprises an amino acid sequence of the claimed peptide range and is less than 30 amino acids in length, specifically 16 amino acids (see Table 1, page 55).

Instant claim 93-94, 96-97 and 134: Peptide fragment amino acids 550-560 anticipates claimed peptide 547-565 as the disclosed peptide consists of an amino acids sequence of the claimed range. (see Figure 1, page 52).

Instant claim 134: Peptide fragment amino acids 797-799 anticipates claimed peptide 785-803 as the disclosed peptide comprises an amino acids sequence of the claimed range (see Table 1, page 55, three amino acids).

Instant claim 134: Peptide fragment amino acids 780-785 anticipates claimed peptide 771-789 as the disclosed peptide consists of an amino acids sequence of the claimed range. (see Figure 1, page 52).

17. Claims 93, 94 and 96 are rejected under 35 U.S.C. 102(b) as being anticipated by Beecher et al (1997).

Beecher et al disclose compositions of peptides obtained from botulinum neurotoxin type A:

Instant claim 93-94,96: Peptide fragment amino acids 545-568 anticipates claimed peptides 533-551 and 547-565 as the disclosed peptide comprises an amino acid sequence of the claimed range (see Table 1, page 705).

Instant claim 93-94,96: Peptide fragment amino acids 559-568 anticipates claimed peptide 547-565 as the disclosed peptide comprises an amino acids sequence of the claimed range. (see Table 1, page 705).

Instant claim 93-94,96: Peptide fragment from amino acid 671-682 anticipates claimed peptide 673-691 as this peptide comprises an amino acid sequence of the claimed peptide range.

Instant claim 93-94 and 96: Peptide fragment amino acids 685-696 anticipates claimed peptide 673-691 as the disclosed peptide comprises an amino acids sequence of the claimed range. (see Table 1, page 705).

Beecher et al anticipates the instantly claimed invention as now claimed.

18. Amended claims 93, 96 are rejected under 35 U.S.C. 102(b) as being anticipated by Oblatt-Montal et al (1995).

Oblatt-Montal et al disclose the instantly claimed invention directed to peptide that comprises at least 6 consecutive amino acids of the range **673-691** of SEQ ID NO 1, wherein the peptide was less than 30 amino acids in length, and comprised residues 659-681 (see page 1491, col. 1, paragraph 3; which corresponds to amino acids 660-682 of instant SEQ ID NO 1), amino acid 673-681 being held in common (8 consecutive amino acids) with instant SEQ ID NO 1. This peptide anticipates the newly amended claims.

19. Claims 93 is rejected under 35 U.S.C. 102(b) as being anticipated by Raju et al (1996).

20. Raju et al disclose the instantly claimed invention directed to peptide that comprises an amino acid sequence of SEQ ID NO 1 the amino acids being selected from peptide **631-649**, The peptide of Raju et al shares 100% sequence identity with amino acids 635-643 of the claimed range. The peptide of Raju et al is referred to as H176-195 and shown in Figure 1, on page 81 and shares 100% sequence identity with SEQ Id No 1 over 9 consecutive amino acids

and stimulated an immune response (see Figure 3, Frame 2, page 83). The disclosed peptide comprises an amino acid sequence that is not more than 30 amino acid in length, wherein the peptide comprised amino acids 635-643 of Botulinum toxin type A. This peptide anticipates the newly amended claims.

21. Claims 93, 96, 134 is rejected under 35 U.S.C. 102(e) as being anticipated by Murphy et al (WO2005,014798, figure 9)(effective filing date March 31, 2003).

Murphy et al disclose a BoNT/A peptide that comprises a fragment of amino acids 715-733 of SEQ ID NO 1, and shares 100% identity over 11 amino acids and is a peptide of 12 amino acids in length (see Figure 9, Botulinum peptide fragment #1). Murphy anticipates the instantly claimed peptide as now claimed.

22. Claims 93 is rejected under 35 U.S.C. 102(b) as being anticipated by Gibson et al (2001, see sequence alignment provided)

Gibson et al disclose a peptide that comprises a fragment of amino acids 743-761 of SEQ ID NO 1, and comprises an amino acid sequence that has one conservative amino acid substitution and comprises amino acids from position 751-756 of SEQ ID NO 1, and is a sequence that is less than 30 amino acids in length (27 amino acids in length). The peptide of Gibson et al anticipates the instantly claimed peptide as now claimed.

23. Claims 93 and 96 is rejected under 35 U.S.C. 102(b) as being anticipated by Kikuyama et al (1995, see sequence alignment provided)

Kikuyama et al disclose a peptide that comprises a fragment of amino acids 813-831 of SEQ ID NO 1, and 100% identity over 6 amino acids at positions 816-821 of SEQ ID NO 1, and is a sequence that is less than 30 amino acids in length (10 amino acids in length). The peptide of Kikuyama et al anticipates the instantly claimed peptide as now claimed.

24. New Claims 134-135 are rejected are rejected under 35 U.S.C. 102(b, copy write 2002) as being anticipated by Atassi (Chapter 38, pages 385-407), as previously applied to claims 93-94, 96, 98.

Atassi disclose the instantly claimed invention directed to peptide that comprises 6 consecutive amino acids of the range **659-677** of SEQ ID NO 1, wherein the peptide was less than 30 amino acids in length, and consisted of residues 663, 664, 665, 666, 667 and 668 (6 consecutive amino acids, see page 385, col. 2, near bottom of first paragraph). This peptide anticipates the newly amended claims.

25. Claims 93-94,96-97,99-101, 134-135 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter because. PG-Pub 200506182 (different inventive entity, no common inventor, earlier filing date, Li and Aoki) disclose compositions of botulinum toxin type A peptides, the peptides consist of amino acids 547-565 ('810, SEQ ID No 69); 589-607 ('810, SEQ ID NO 73); 631-649 ('810, SEQ Id No 74); 715-733 ('810, SEQ ID NO 78, 77); 743-761 ('810, SEQ ID NO 80) 785-803 ('810, SEQ ID NO 13, 28, 83); 981-999 ('810, SEQ ID No 95); 1051-1069 ('810, SEQ ID NO 99), 1275-1296 ('810, SEQ ID NO 105)

(see all figures and disclosure). Li and Aoki anticipate the instantly claimed invention as now claimed.

Double Patenting

26. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

27. Claims 93-94,96-97,99-101, 134-135 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22, 29-30, 70-71(toxin type A) of copending Application No. 10/715,810 (PG-Pub 200506182 (different inventive entity, no common inventor, but common assignee). Although the conflicting claims are not identical, they are not patentably distinct from each other because the inactive botulinum toxin type A compositions of Application 10/715,810 are defined to be rescue agents which are shown in Application 10/715,810's figures and include peptides with amino acids 547-565 ('810, SEQ ID No 69); 589-607 ('810, SEQ ID NO 73); 631-649 ('810, SEQ Id No 74); 715-733 ('810,

SEQ ID NO 78, 77); 743-761 ('810, SEQ ID NO 80) 785-803 ('810, SEQ ID NO 13, 28, 83); 981-999 ('810, SEQ ID No 95); 1051-1069 ('810, SEQ ID NO 99), 1275-1296 ('810, SEQ ID NO 105). This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

28. This is a non-final action.

29. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. PG-Pub 20040101534 is cited to show SEQ ID NO 4, a peptide of 14 amino acids of which 10 are identical or a conservative amino acid substitution thereof and aligns with peptide 631-649 at positions 633-643.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp
November 7, 2006

MARK NAVARRO
PRIMARY EXAMINER